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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,815	10/18/2001	Wolfgang Muhlbauer	GLAWE-06599	5359

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/02/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

10/041,815

Applicant(s)

MUHLBAUER ET AL.

Examin r

Shahnam Sharareh

Art Unit

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Peri d f r Reply
-- The MAILING DATE of this communication appears on the c ver sheet with the corresp ndence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/18/01, 5/15/03 .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____ .
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____ .

DETAILED ACTION

1. Claims 12-25 are pending. Applicant's election of the pending claims and cancellation of claims 26-43 in Paper No. 8, is acknowledged.

Priority

2. Applicant is advised of possible benefits under 35 U.S.C. 119(a)-(d), wherein an application for patent filed in the United States may be entitled to the benefit of the filing date of a prior application filed in a foreign country. However, Applicant is reminded that in order for a patent issuing on the instant application to obtain the benefit of priority based on priority papers filed in parent Application No. 09/169559 under 35 U.S.C. 119(a)-(d) or (f), a claim for such foreign priority must be made in this application. In making such claim, applicant may simply identify the application containing the priority papers.

Specification

3. As provided in 37 CFR 1.77(b), the specification of a utility application should include specific sections in order. The instant disclosure is objected to because the heading for the following sections are missing:

- ☐ There is no section describing background of the invention.
- ☐ There is no brief description of drawing.
- ☐ There is no brief summary of the invention.
- ☐ There is no detailed description of the invention.

Each of the above items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not

Applicable." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999).

The term "liquid paraffin" in claim 25 is used by the claim to mean "a wax of liquid paraffin", because claim 25 is dependent on claim 12 and the paraffin of claim 12 is enumerated as a wax. However, the accepted meaning of "wax" is a viscous, solid or pliable liquid substance of mineral origin consisting essentially of a high molecular weight hydrocarbons. (see Webster II New Riverside University Dictionary, 1994). Accordingly, the term "liquid paraffin" is indefinite because it is directed to liquid form of paraffin. The specification does not clearly redefine the scope of such term. Nor does it clearly limit the scope of such term to only viscous, pliable liquid of paraffin. Accordingly, the term "liquid paraffin" in view of its base claim 12 appears ambiguous.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 12, 16 -18, 20, 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark US Patent 4,005,191.

The instant claims are directed to methods of dressing a wound comprising applying to a patient a composition comprising a wax such as petrolatum or paraffin and a metal hydroxide.

Clark discloses methods of treating various types of skin wounds comprising applying to a wound topical compositions comprising petrolatum, a metal hydroxide such as magnesium hydroxide, an additional substance such as lanolin base in amounts of about 50% by weight, which falls within the limitations of claim 18. (see abstract; col 5, lines 5-67; col 6, lines 40-56; Examples I-V, cols 7-9). Lanolin base of Clark is a purified wool fat of sheep, which meets the limitations of genus fats of claim 17. (col 6, lines 13-15). Petrolatum used by Clark is in amounts ranging from 25-50% weight, which meets the limitation of claim 16. (see col 5, lines 15-18 and all examples wherein petrolatum is used, col 11, lines 55-63).

The limitation of claim 24 is also inherent to the composition of Clark, because the alkalinity of the composition is provided by magnesium hydroxide or aluminum hydroxide. Since the compositions of Clark essentially contain diluted magnesium

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hydroxide or aluminum hydroxide in water, lanolin, and petrolatum; they, inherently delay the alkalinity release on the skin when they are compared to direct application of the magnesium hydroxide or aluminum hydroxide to the skin. Therefore, since compositions of Clark meets all components of the instant claims, it also exhibits the functional properties of claim 24. Accordingly, Clark anticipates the limitations of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 12, 14-17, 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Futami et al US Patent 4,740,245 ('245)

Futami '245 discloses compositions for use in root canal comprising a wax-like component such as paraffin wax or Japan wax, a metal hydroxide such as calcium hydroxide, at least a one additional substance such as guttapercha, a filler such as

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microcrystalline wax or kaolin (see abstract; col 4, lines 16-62; col 6, lines 1-5, 21-24 and 46-60; col 8, lines 21-65; col 10, lines 30-50; col 11, lines 5-11 and 20-31; col 12, lines 15-21 and lines 46-49).

Futami's compositions comprise a wax like components in amount of up to about 20% weight (col 5, line 50-col 6, line 9, claim 14), which meets the limitations of claim 12 and 16. Futami's composition also contains inorganic filler such as alkaline earth metal hydroxide in amounts of about 50% which meets the limitations of claims 22. (col 4, lines 58-66; col 5, lines 1-5; col 9, lines 15-27). Futami's composition further contains an additional substance such as beeswax or microcrystalline wax which meets the limitation of claim 17. (see col 8, lines 21-35). Finally, since Futami's composition contains all elements of the instant claims, it can also exhibits the functional properties of claim 24. Futami does not explicitly teach methods of treating a wound.

However, even though Futami does not explicitly set forth methods of treating a wound on a fractured surface in a bone such as root canal cavity, it would have been obvious to one of ordinary skill in the art at the time of invention to employ Futami's composition for treating a wound in the surface of a bone, because as taught by Futami, the intended purpose of Futami's compositions is treating root canal filling and root canal is a wound in a bone. Thus the ordinary skill in the art would have had a reasonable expectation of success in using Futami's compositions for its intended use.

7. Claims 12, 14-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Futami et al US Patent 4,740,245 ('245) in view of Futami US Patent 5,051,130 ('130).

Futami '245 teaches compositions that are used for treating bony wounds within the mouth, comprising up to about 20% wax and up to 50% weight of inorganic fillers such as calcium hydroxide. Futami does not teach the methods of using his compositions. Further, Futami does not teach the use of vegetable oils or castor oil in his compositions.

Futami '130 is used to merely show that castor oil or vegetable oils such as olive oil are well-recognized additives to setting agent compositions. Accordingly, they are employed to optimize the setting acceleration (col 6, lines 19-41). In addition, such agents can facilitate handling of wound products and are readily employed to form paste consistency of dental sealing compositions. (see col 6 line 24-26, col 11, lines 20-35).

It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, 1072 (CCPA 1980). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use Futami's '245 compositions, as taught in his example 2, and add a vegetable oil or castor oil to improve the handling and its setting characteristics, because both Futami '245 and '130 essentially are used for the same purpose and Futami '130 provides that vegetable oils or castor oil improve handling of the dental paste compositions. Subsequently, as reasoned in paragraph 5, it would have been obvious to one of ordinary skill in the art at the time of invention to

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employ such dental compositions for their own intended use and treat wounds in the jaw bone.

8. Claims 12, 14-17, 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Futami et al US Patent 4,740,245 ('245) in view of Remington: The Science and Practice of Pharmacy, 19th edition (page 1400-01).

Futami's teachings are described above. Futami fails to explicitly teach liquid paraffin.

Examiner takes the position that liquid paraffin, construed as soft paraffin, and paraffin are functional equivalents and thus are interchangeable in the art. To support this position, Applicant's attention is drawn, for example, to recitations of soft paraffin, paraffin jelly, petroleum jelly, white petrolatum, and white soft paraffin in Remington at page 1400. Accordingly, all such compounds are oleaginous ointment bases providing the same function in compositions. Thus, Examiner considers liquid paraffin, white petrolatum, petrolatum and paraffin as functional equivalents. (see Remington, at 1400).

Thus, as petrolatum, soft paraffin, white petroleum jelly, white soft paraffin are art recognized functional equivalents, it would have been obvious to one of ordinary skill in the art at the time of invention to replace paraffin's of Futami '245 with petrolatum or petroleum jelly, because the ordinary skill in the art would have had a reasonable expectation of success in observing the same benefits.

9. Claims 12-15, 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dietz US Patent 5,585,117 in view of Scafidi US Patent 5,683,683.

Dietz teaches that a mixture of calcium hydroxide, oleum pedium tauri (otherwise known as neatfoots oil) and white petroleum jelly stimulates collagen reformation after a dental surgery or a root canal procedure (see col 2 lines 20-45). Dietz teaches methods of filling a bone wound by applying his composition to drilled jaw bones (see example 3). Dietz compositions contain neatsfoot oil, which is excluded as a component in the instant claim 12. The compositions used by Dietz also do not contain a vegetable oil.

Scafidi is solely used to establish that neatsfoot oil, white petrolatum, castor oil, vegetable oils such as jojobo oil, sunflower seed oil and animal fats such as lanolin oil are functional equivalents in the art, because they all function as oleaginous substance within topical compositions and thus provide the same intended use. (col 10, lines 11-25). Accordingly, they are interchangeable in the art of pharmaceutical formulation.

Dietz meets all the limitations of pending claims, except that it employs compositions that contain neatsfoot oil rather than vegetable oils, fats or waxes of the instant claims 12, 17-19. However, as shown by Scafidi, neatsfoot oil, jojoba oil, castor oil, and sunflower oil are art-recognized equivalents. Accordingly, absence of showing unexpected results, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute neatsfoot oil of Dietz with any of white petrolatum, jojobo oil, castor oil or sunflower oil, lanolin oil, because, as suggested by Scafidi, they are art recognized equivalents and the ordinary artisan would have had a reasonable expectation of observing similar effects when using one in place of the other.

Conclusion

10. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.



Shahnam Sharareh, PharmD
Patent Examiner, Art Unit 1617

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June 29, 2003